श्री अमर सिंह: बहुत-बहुत धन्यवाद, मान्यवर।

श्री महेन्द्र मोहन: धन्यवाद, सभापति महोदय। मैं माननीय मंत्री जी से यही जानना चाहता हूं कि यह जो सवाल है कि जो oceanic ship, जो 250 टन एस्बेस्टस और toxic material लेकर आ रहा था, उन्होंने उत्तर दिया है कि उसके बारे में कोई जानकारी नहीं है। कृपया यह पता करके अवश्य बताएं कि यह जहाज अलग में आया अथवा नहीं आया और यदि आया, तो क्या उसे तोड़ने की अनुमति दी गई अथवा नहीं दी गई? इसकी जानकारी सदन को और हमको अवश्य दें।

श्री राम विलास पासवान: सर, अभी हमारे पास जो जवाब है, क्योंकि हमारे पास क्वैश्चन 10 दिन पहले, 7 दिन पहले आता है, उसमें हम लोग जानकारी इकट्ठा करते हैं। हम इसको दोबारा confirm कराएंगे और दोबारा पता लगाएंगे कि जो जवाब 'No' में दिया गया है, as reported, उसको दोबारा जांच कर हम आपको बता देंगे।

Heavy metals in ayurvedic medicines

*264.DR. JANARDHAN WAGHMARE:††
SHRIMATI SHOBHANA BHARTIA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the American drug regulator, Food and Drug Administration (FDA), has recently revised and issued its import alert following recent findings that ayurvedic drugs shipped from India contained high level of toxic heavy metals;

(b) if so, the facts thereof and the details of the companies and names of the ayurvedic drugs to which Government have allowed export and were found to contain detectable levels of heavy metals; and

(c) the steps Government proposes to take to ban manufacture/ sale / export of such ayurvedic drugs which contain toxic heavy metals?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMADOSS): (a) to (c) A Statement is laid on the Table of the House.

Statement

(a) The Website of the US Food and Drug Administration (US.FDA) states that "Ayurvedic products are generally not reviewed or approved by the Food and Drug Administration (FDA)". However, the US.FDA has urged the consumers to use caution with Ayurvedic products due to the presence of metal containing products exceeding permissible limits found in them, in the wake of an article published in the August 27th, 2008, issue of the Journal of the American Medical Association (JAMA) which stated that 1/5th of the US manufactured and Indian manufactured Ayurvedic products bought through websites on the internet contain detectable level of lead, mercury or arsenic.

(b) An internet search using 5 internet search engines and the search terms 'Ayurveda and Ayurvedic Medicine' identified 25 websites offering / selling Ayurvedic products. From the 673 identified Ayurvedic products, 230 medicines were randomly selected for purchase between August - October, 2005 and orders placed for their purchase. However, the researchers received only 193 products which were subjected to an analysis using x-ray, fluorescence, spectroscopy and nearly 21% of these products were found to contain detectable levels of lead, mercury or arsenic.

†† The questioni was actually asked on the floor of the House by Shri Janardhan Waghmare.

As per this article, detectable levels of lead, mercury or arsenic were found in the following Indian manufactured Ayurvedic products:

S.No.	Name of Indian Company	Name of Products
1.	Goodcare Pharma	Ezi Slim
2.	Baidyanath	Ekangvir Ras, Agnitundi Bati, Brahmi, Amoebica, Arogyavardhini Bati
3.	Maharishi Ayurved	Vital Lady, Worry Free
4.	Sharangdhar	Ayu-Arthri-Tone,
	Pharmaceuticals	Ayu-Hemoridi-Tone, Ayu-Leuko-Tone, Ayu-Niphro-Tone

This study followed a previous study published in JAMA on December 15, 2004, which found that one out of five Ayurvedic 'herbal medicine products' produced in South Asia and available in South Asian grocery stores in Boston contained potentially harmful levels of lead, mercury, and/or arsenic.

(c) The Government have taken immediate steps to test the samples appearing in Journal of the American Medical Association (JAMA) article from reputed National Accreditation Board of Laboratories (NABL) accredited laboratories. The Central Council for Research in Ayurveda and Siddha (CCRAS) has undertaken a study to see the toxicity/safety profile of metal based bhasmas. The study is being carried out in Indian Toxicological Research Center (ITRC), Council for Scientific and Industrial Research (CSIR), Lucknow. Pharmacopoeial Laboratory of Indian Medicine (PLIM), Ghaziabad has been directed to procure samples of all the products mentioned in both the JAMA articles and send them to Indian Institute of Chemical Technology (IICT), Hyderabad for heavy metal analysis by electron spectroscopic chemical analysis as well as X-ray fluorescence spectroscopy. The manufacturers of Ayurvedic medicines mentioned in JAMA articles have been directed to get safety/toxicity studies carried out for their products by National Accreditation Board of Laboratories / Good Laboratories Practices (NABL/GLP) accredited laboratories and send their report in respect of acute, sub acute and chronic safety/toxicity drug studies. After examination it was found that no Indian exported herbal ayurvedic medicine contained toxic heavy metals more than the permissible limit. As far as purely herbal Ayurvedic formulations are concerned, presence of heavy metals was not detected. As regards herbo-mineral and herbo-metallic preparations, metals are an essential ingredient of these formulations and, therefore, are bound to be present in these, however they are permitted to be used only after due purification and only in small quantities to act as catalysts for activation of other herbal ingredients in order to increase the efficacy of the medicines. The metallic preparations in the form of compounds of metals triturated in the form of 'Bhasmas' are rendered safe after purification with herbs and burning in fire for a prescribed number of times.

Further, a Press release was issued on 2nd September, 2008 with detailed comments by the Department of AYUSH to counter the article published in JAMA. The following orders have also been issued by the Central Government to ensure safety and efficacy of AYUSH products in the country and abroad:-

i) Government has introduced mandatory testing for heavy metals in all purely herbal Ayurveda, Siddha and Unani medicines to be exported with effect from 01.01.06 onwards. This has been done to meet the regulatory requirements of importing countries.

ii) State Drug Licensing Authorities have been directed to ensure full compliance by all ASU drug manufacturers of the provisions of Rule 161 (1) and (2) relating to displaying on the label of the container or in a leaflet to be inserted in the package of an ASU drug, the true list of all the ingredients used in the manufacture of the preparation together with the quantity of each of the ingredients incorporated therein.

iii) A research project has been sanctioned to various laboratories of Council of Scientific and Industrial Research (CSIR) under the Golden Triangle Partnership Project to study the physiochemical characteristics of 8 most widely used Bhasmas and to carry out their toxicity studies.

iv) Good Manufacturing Practices have been made mandatory for all Ayurveda, Siddha and Unani drug manufacturing units in the country.

v) Department of AYUSH has discussed with Minister of Commerce to set up an AYUSH Export Promotion Council under the Department of AYUSH to take care of critical issues like testing and certification of Ayurveda, Siddha and Unani medicines for export.

vi) Government have constituted Pharmacopoeia Committees of Ayurveda, Siddha and Unani systems of medicines for preparation of Pharmacopoeias to ensure the quality of Ayurveda, Siddha and Unani drugs.

vii) Captain Shreeniwas Murti Drug Research Institute for Ayurveda, Chennai, IITR, Lucknow and Sri Ram Institute for Industrial Research, New Delhi, have analyzed about 600 plants and it was found that lead arsenic and mercury levels were within the permissible limits.

viii) State Licensing Authorities have been directed to constitute an Expert Committee under the provision of Rule 154 (2) of the Drugs and Cosmetics Rule, 1945, for streamlining the system for licensing of patent and proprietary Ayurveda, Siddha and Unani products.

DR. JANARDHAN WAGHMARE: Sir, my first supplementary is whether there is any regular mechanism or a regular agency or an assessment board through which the quality of Ayurvedic products is reviewed, assessed or examined?

DR. ANBUMANI RAMADOSS: Sir, I would like to submit that the quality not only for Ayurvedic but the ASU drugs, that is, Ayurvedic, Siddha and Unani, we have, in fact, the Drug Controller General of India, who is the overall authority on that, and we have the State authorities who oversee the quality and the standard of all these units. Since 2003-04, we have made for all of them mandatory that they have to be GMT compliant, that is, good manufacturing practice. Without a GMT, no unit in India can function and we do not give licence to them so that we have a basic qualification of all these units. Nevertheless, Sir, there are approximately about 9700 units all over the

country manufacturing all these AYUSH drugs and we still have some shortfalls. I accept that those shortfalls are there which are due to the inefficiency of some of the States to oversee and monitor these parameters, which we have entrusted to the States. We are confident that in due course all of them may be set right.

DR. JANARDHAN WAGHMARE: Sir, my second supplementary is this, Sir. Ayurvedic being an indigenous system, in what way the Government is promoting Ayurveda? Has the Government explored any global market for the Ayurveda products?

DR. ANBUMANI RAMADOSS: Sir, firstly, I would like to invite the hon. Member to my office at his convenience, or, at least, I will have a meeting with my Secretary to see firsthand what we are doing in not only in Ayurvedic but in the whole Indian system of medicines. We have a separate Department, called the Department of AYUSH with a Secretary, Joint Secretaries, and other senior officials. Today the budget of this Department is approximately about more than Rs.1000 crores per year. We have a National Medicinal Plants Board also in that Department. In fact, when I took over as the Minister about two-and-a-half years ago, the total budget was about Rs.200 crores, which is now nearly Rs.1000 crores. There is so much increase. Definitely, we are promoting our own system. Our forefathers had founded this system and this is the system where we have both preventive and promotive healthcare and that is what we are trying to imbibe in it. In fact, now under the National Rural Health Mission, we are engaging these traditional Indian system doctors whether Ayurvedic doctors, Siddha, or any other doctors in the primary health centres and till date approximately 4000 doctors have been employed there and we have given them a lot of leverage. State drug controlling testing labs have been empowered. They have been modernised. Nearly Rs. 1.5 crores have been given to nearly 25 State drug controlling labs. In fact, to protect the patent Ayurveda system and all the other Indian systems also we have a concept called the traditional knowledge digital library where we have compiled nearly about one lakh ninety five thousand formulations in five languages and we are trying to register this in about eleven countries who are giving the maximum patents so that the misuse of patents of our own system is not there. In Delhi, we are now going to start a National Institute of Ayurveda on the lines of the All India Institute of Medical Sciences. But, once again, I would like to invite the hon. Member also to my office; if he comes anytime according to his convenience, I would show him. Then, there is a National Institute of Ayurveda in Jaipur, National Institute of Unani in Bangalore, National Institute of Homoeopathy in Calcutta, National Institute of Siddha in Chennai, National Institute of Yoga here in Delhi in Ashoka Road.

MR. CHAIRMAN: Shrimati Brinda Karat.

SHRIMATI BRINDA KARAT: Sir, my question to the Minister is ...*(Interruptions)*...

SHRI SHARAD PAWAR: *Ramdevwala*?

SHRIMATI BRINDA KARAT: Partly. My experience with that is prompting this question, and, Sir, that concerns the protection of the consumer or the patient who is taking Ayurvedic drugs. It is unfortunate that the FDA has now put us in a situation where we are talking about better practices in GMP, whereas as regard the efficacy of Ayurvedic drugs, at least in my mind there is no doubt about

it, and so many patients have been cured by taking such indigenous medicines. However, the consumer has to be protected by, at least, ensuring that the properties in that medicine are properly displayed on the packet or in the packaging, and even today I know certain very well-known pharmacies which are also being promoted by the Government, and I believe that certain post offices have been directed to sell that medicine or it has allowed that medicine to be sold through the post offices. I would like to know from the Minister whether that is correct or not. But along with that, even today, for example, a medicine for epilepsy is sold in a plastic packet with absolutely no information given as to what exactly is there in the powder. So, is the Health Minister going to ensure that the properties contained in those medicines are properly displayed? Whether it is of animal origin or whether it is of any other origin, at least, the consumer taking it should know that, I mean, what he or she is taking.

DR. ANBUMANI RAMADOSS: Sir, today, we have a law which says that all the ingredients should be mentioned in the labelling of these products.

SHRIMATI BRINDA KARAT: Will you take action if they are not doing it?

DR. ANBUMANI RAMADOSS: I will come to your question. Not only the ingredients, whether it is a scheduled drug, all these should be mentioned in all labelling. But our Indian system of medicine is individual oriented. Some of these treatments are individual oriented. As an individual, you come there. They have a formulation. They have drugs and herbs and all that, and they mix them up and give to an individual patient, according to the individual capacities or the individual problems. You have to prepare it freshly. All these issues are there. The logistics and practical issues are to be addressed. Nevertheless, these drugs which are manufactured by these units – manufacturing units which are nearly about 9000 of them – are GMP-compliant. All of them have to have these ingredients labelled when they are labelling. Also, Sir, two or three years ago, we have made it mandatory that there should be self-testing, and all these products should be self-tested and also, for the export products there should be self certification from NABL accredited labs. Till such time, we are able to put in place all these mechanisms of all the Central and State drug testing labs. Sir, I would like to go to the basic issue. She spoke about FDA.

Sir, there are, basically, two types drugs. The first one is pure herbal drugs which do not contain any metals or minerals. The second type is herbo-mineral or herbo-metalic drugs. Metals and minerals are the components of these drugs. These have been used for centuries and have been proven. These metals and minerals go through a process of purification, heating, absorption, etc. In its purity form all this is there. The US.FDA does not test any non-allopathic drugs. They test only allopathic drugs. For others, they just give advice. I understand that there have been some issues about the articles written in Boston and other areas where it was mentioned that Indian drugs or Ayurvedic drugs have heavy metals or metallic components and all that. They are drugs in India. In the USA they are food supplements. They are not drugs. They do not undergo any process there. So, it is the onus of the importing country also to see what all is there. Also, we have tested a lot of these drugs and found a majority of them have a permissible WHO level of metal components. So, there are different types of permissible levels for a drug and a food item. It is a complex issue. Nevertheless, I would like to reassure the hon. Member and agree with him that all the ingredients have to be mentioned on all the packets which are being sold in these units.

SHRI KUMAR DEEPAK DAS: Sir, as per the provisions under the Drugs and Cosmetic Rules, 1945, first there was a system of licence. Now, we found lead, mercury, arsenic in some drugs up to 21 per cent. So, my pertinent question to the hon. Minister is what action he has taken against those manufacturing companies which are involved in this. Thank you.

DR. ANBUMANI RAMADOSS: Sir, I have already answered that question. There are both types pure herbal and herbo-metallic or herbo-mineral drugs which has a component of mineral and metals like lead or arsenic or mercury of drugs and their formulations are like that. And, we have our own standards. The Government of India have accepted the WHO Standards of permissible levels in these drugs. There are cases that we have also tested a lot of these drugs ourselves and found that most of these drugs have the permissible levels. Nevertheless, the institutions that do not have or the units which manufacture drugs which have higher than the permissible levels of metals, etc., we have sent notices and they have been closed. We have given the responsibility to the State authorities and we are also trying to set up infrastructure and a drug testing lab.

Apart from this, a number of studies have also been carried out. A concept called the Golden Triangle was constituted by the CSIR, ICMR and the AYUSH Department with an estimated amount of Rs. 120 crores. We are trying to find out the mineral components in 'Bhasmas' and nearly 8 'Bhasmas' have been taken up and toxicity and safety study has been done. In fact, out of 8 studies, Report on one Study - Naga Bhasma – has been submitted called by the PLIM Laboratory in Noida. So, we are going through a lot of process. It is a continuous process. Again, I would like to assure the hon. Member that we are trying, definitely, our best. But, we still have some way to go. I still acknowledge that. We are depending on the State Government to function and to implement what we are trying to do at the Centre.

SHRI SU. THIRUNAVUKKARASAR: Sir, after the import alert received from the US.FDA, naturally, our exports would have come down and the earnings of foreign exchange would have also come down. After due examination of our laboratories in India, it was found, as per the hon. Minister's Report, that no Indian exported herbal Ayurvedic medicine contained toxic heavy metals more than the permissible limit. As far as the pure herbal Ayurvedic formulations are concerned, presence of heavy metals was not detected. In such a case, what steps are taken by the Health Ministry to promote the export of Ayurvedic medicines, so that we can earn more and more foreign exchange for the country?

DR. ANBUMANI RAMADOSS: Sir, now-and-then, we get some of these reports about studies being done. And, Sir, about this study, which was done in Boston, I would say that this was picked up from the Internet.

From Internet we don't know about the source of drug. Any country in the world could manufacture these drugs and say them as Ayurvedic drugs. We don't know the source.

Nevertheless, we are discussing with the Ministry of Commerce for setting up of AYUSH Export Promotion Council so as to facilitate the testing and certification so that there is more promotion of

these drugs. And, in fact, if any of the issues came, immediately rejoinders have been given. We have asked the expert Committee, the Central council of Research in Ayurveda and Siddha, to initiate the process and give rejoinders saying that these drugs are safe.

MR. CHAIRMAN: Question Hour is over.

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WRITTEN ANSWERS TO STARRED QUESTIONS

Disbursement of funds by NAFED to private parties

*265.SHRI S.S. AHLUWALIA: Will the Minister of AGRICULTURE be pleased to state:

(a) whether the National Agriculture Cooperative Marketing Federation (NAFED) has disbursed huge funds to private parties under the pretext of promoting exports of even non-agricultural items like iron-ore;

(b) if so, the volume of funds so given to private parties indicating details of identities of recipient private parties, along with dates of disbursal to respective parties and the terms thereof;

(c) whether these parties have largely defaulted in repaying the funds as per the terms;

(d) if so, the details thereof, indicating its impact on the financial health of NAFED; and

(e) the steps taken, if any, for recovery of the outstanding dues from those parties?

THE MINISTER OF AGRICULTURE (SHRI SHARAD PAWAR): (a) to (e) NAFED, which is a national cooperative society governed under the provisions of Multi-State Cooperative Societies Act, 2002 has reported that it has diversified its business activities and undertaken new business initiatives in Public Private Partnership mode. Under this, NAFED disbursed funds amounting to Rs. 3962.24 crore to 62 parties. Out of 62 parties, 33 have settled their accounts. A Statement giving details of 62 parties to whom funds have, been disbursed by NAFED, year-wise, amount-wise, date-wise and amount due as on 31.10.2008, is given in the Annexure [*See* Appendix 214, Annexure no. II] Out of Rs. 3962.24 crore funds disbursed by NAFED under such business activities, the amount recovered as on 31.10.2008 is Rs. 2886.36 crore and total amount due is Rs. 1438.71 crore including interest and service charges as intimated by NAFED.

The major terms and conditions for financing under tie-up/PPP business by NAFED were mainly (i) generally Investment Ratio ranging from 80:20 (80% investment to be made by NAFED and 20% being contributed by business associate) to 90:10 to various associates was allowed except in some cases where Letter of Credit were opened against fixed security deposit, (ii) rate of interest on investment of NAFED ranged from 7% to 10% p.a. to various associates, (iii) one time service charges on ex-godown/CIF/FOB value of stock ranged from 1% to 1.50% to various associates, (iv) stocks procured/imported were to be stored in name of NAFED and pledge in favour of NAFED,